



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005**

January 20, 2005

The Cancer Center of Hawaii, LLC
ATTN: Ronald W. Frick
Radiation Safety Officer
2226 Liliha Street
Honolulu, HI 96817

SUBJECT: NEW LICENSE

Please find enclosed License No. 53-27797-01. An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14)(iv). You should review this license carefully and be sure that you understand all conditions. If you have any questions, you may contact me at 817-276-6552.

Please note, the NRC can not approve Item 23 of your application, under "Additional Information supporting use of GliaSite RTS System," which states in part your request to authorize changes to your radiation safety program within the criteria provided. Your NRC radioactive materials license is of limited scope (i.e., not broad scope license) and therefore, you can not make changes to your radiation safety program, from that which was submitted and included as part of your license (e.g., License Condition 15.) However, you may make changes to those portions of your radiation safety program which are not included in License Condition 15. Additionally, if the guidance on the NRC web page regarding GliaSite Radiation Therapy System changes, then you may make corresponding changes to your radiation safety program.

The NRC needs your Taxpayer Identification Number in order to make payments (refunds). Please complete and return the self-addressed, stamped NRC Form 531, "Request for Taxpayer Identification Number," which is enclosed for your convenience.

NRC expects licensees to conduct their programs with meticulous attention to detail and a high standard of compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your radiation safety program according to the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. In accordance with 10 CFR 30.36(d), notify NRC, promptly, in writing within 60 days, and request termination of the license:
 - a. When you decide to terminate all activities involving materials authorized under the license whether at the entire site or any separate building or outdoor area;
 - b. If you decide not to acquire or possess and use authorized material; or
 - c. When no principal activities under the license have been conducted for a period of 24 months.

2. In accordance with 10 CFR 35.14, notify the NRC no later than 30 days after:
 - a. The date that the licensee permits an individual to work as an authorized user or an authorized medical physicist under 10 CFR 35.13(b)(1) through (b)(4);
 - b. An authorized user, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues duties under the license or has a name change;
 - c. The licensee's mailing address changes;
 - d. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in 10 CFR 30.34(b); or
 - e. The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 35.100 or 35.200.
3. Request and obtain a license amendment before you:
 - a. Change Radiation Safety Officers;
 - b. Order byproduct material in excess of the amount, radionuclide or form authorized on the license;
 - c. Add or change the areas or address(es) of use identified in the license application or on the license, except for areas of use where byproduct material is used only in accordance with either 10 CFR 35.100 or 35.200; or
 - d. Change the name or ownership of your organization.
4. Submit a complete renewal application or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.

In addition, please note that NRC Form 313 requires the applicant, by signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant. Since the NRC also accepts a letter requesting amendment or renewal of an NRC license, the signatory for such a request should also be the licensee or certifying official rather than a consultant.

NRC will periodically inspect your radiation safety program. Failure to conduct your program according to NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC may result in enforcement action against you. This could include issuance of a notice of violation; imposition of a civil penalty; or an order suspending, modifying, or revoking your license as specified in the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600.

The NRC no longer publishes the NRC Rules and Regulations loose leaf supplements due to budget constraints. However, an electronic version of the NRC's regulations is available on the NRC Web site at www.nrc.gov. To view these regulations, highlight "Electronic Reading Room" and choose "Regulations" on the drop down menu. An electronic version of the NUREG-1556 Series publications is also available on the NRC Web site. To view these guidance documents, highlight "Electronic Reading Room," choose "All Document Types" on the drop down menu. Scroll down to "NUREG-Series Publications" and select "Publications Prepared by the NRC Staff." Then, choose "NUREG-1556" from the table and select the appropriate volume(s) for your license type.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-36775
License: 53-27797-01
Control: 470300

Enclosure: As stated

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. The Cancer Center of Hawaii, LLC	3. License number 53-27797-01
2. 2226 Liliha Street Honolulu, Hawaii 96817	4. Expiration date January 31, 2015
	5. Docket No. 030-36775 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material identified in 10 CFR 35.400	A. Sealed Sources (Best Medical International, Inc. Model Nos. 2331-2335, Mentor dba Mills Biopharmaceuticals, Inc. Model No. I-125SL, Amersham Health/Medi-Physics, Inc. Model 6733 and 6735, Theragenics Corporation Model I25.S06 and Model 200, Implant Sciences Corporation Model 3500)	A. 1 curie
B. Iridium-192	B. Sealed sources (Nucletron Model No. 105.002, manufactured by Mallinckrodt Medical BV or AEA Technology, Inc.)	B. 2 sources not to exceed 12 curies each
C. Iodine-125	C. Liquid as Iotrex™	C. 8 curies
D. Depleted Uranium	D. Metal	D. 500 kilograms

9. Authorized use:
- A. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
 - B. One source for medical use described in 10 CFR 35.600, in a Nucletron MicroSelectron-HDR Model 105.999 remote afterloading brachytherapy unit, in which the source activity may not exceed 10 curies at the time of installation. A second source assembly in its shipping container, as necessary, for replacement of the source assembly in the HDR remote afterloader unit.
 - C. For use in the Proxima Therapeutics' GliaSite Radiotherapy System.
 - D. Shielding in a linear accelerator.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
53-27797-01

Docket or Reference Number
030-36775

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at:
- A. The Cancer Center of Hawaii, 2226 Liliha Street, Honolulu, Hawaii
 - B. St. Francis Medical Center, 2230 Liliha Street, Honolulu, Hawaii
11. The Radiation Safety Officer for this license is Ronald W. Frick.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as authorized user, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14:
 - B. The following individuals are authorized users for materials and uses indicated:

Materials and Use

Paul DeMare, M.D.	35.400, Iridium-192 HDR radiotherapy, Iodine-125 and depleted uranium
Vince Brown, M.D.	35.400, Iridium-192 HDR radiotherapy, Iodine-125 and depleted uranium
John Lederer, M.D.	35.400, Iridium-192 HDR radiotherapy, Iodine-125 and depleted uranium
Than Huynh, M.D.	35.400, Iridium-192 HDR radiotherapy, Iodine-125 and depleted uranium
Christine Liu, M.D.	35.400, Iridium-192 HDR radiotherapy, Iodine-125 and depleted uranium
Laeton Pang, M.D.	35.400, Iridium-192 HDR radiotherapy, Iodine-125 and depleted uranium
Mark Kanemori, M.D.	35.400, Iridium-192 HDR radiotherapy, Iodine-125 and depleted uranium
Charles Yamashiro, M.D.	35.400, Iridium-192 HDR radiotherapy, Iodine-125 and depleted uranium
Winlove B. Suasini, M.D.	35.400, Iridium-192 HDR radiotherapy, Iodine-125 and depleted uranium

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
53-27797-01

Docket or Reference Number
030-36775

C. The following individuals are authorized medical physicists:

Materials and Use

Quan A. Nguyen, M.S.

Iridium-192 in a High Dose Rate Afterloader
Brachytherapy Unit for calibrations, spot-checks, and
training

Hong Guo

Iridium-192 in a High Dose Rate Afterloader
Brachytherapy Unit for calibrations, spot-checks, and
training

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
14. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated December 8, 2004
B. Letter dated January 19, 2005

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Date: January 20, 2005

By: _____

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch
Region IV
Arlington, Texas 76011